Remarks

This Amendment is in response to the Office Action dated July 2, 2007.

Restriction

In response to the restriction requirement the applicant has cancelled claims 1-5, 8, 12, 15-19 and 27-28 and has amended claims 6-7, 9-11, 13-14, 24-26 and 29-30 to depend directly or indirectly from method claim 20. Claims 6-7, 9-11, 13-14, 20-26 and 29-30 are currently pending and all fall within the elected method claim group. Withdrawal of the restriction requirement as to 6-7, 9-11, 13-14, 24-26 and 29-30 is therefore respectfully requested.

Claim Objection

Claim 20 has been objected to. The Office Action states that "the phrase --at least one of -- is missing in line 14 of claim 20, between the words 'and' and 'the.'" Applicant does not agree. The recitation in question ("and the two regions are provided with differing amounts of said crystallization modifier") is comparing the two regions to each other. It does not make sense to refer to only one of the regions when making this comparison. What would it differ from? Withdrawal of this objection is respectfully requested.

Claim Rejections 35 USC §103

Claims 20-22 have been rejected under 35 USC §103(a) for obviousness from Nelson et al. (US 6,596,2960, in view of Katayama et al. (US 6,552,123). The Applicant traverses the rejection. Reconsideration is requested.

To support an obviousness rejection, the cited prior art must be applied in the context of

their significance to a technician at the time the invention was made, without knowledge of the applicant's invention. It is impermissible, simply to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template, picking and choosing among isolated disclosures in the various documents to supply elements to fill the gaps. US patent law is replete with cases that illustrate this principle. See e.g. *In re Kotzab* 55 USPQ2d 1313 (Fed. Cir. 2000); *Winner International Royalty Corp. v. Wang*, 53 USPQ2d 1580, 1586 (Fed Cir 2000); *In re Dembiczak*, 50 USPQ2d 1614, 1616-17 (Fed. Cir. 1999); *In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988); *In re Gorman,* 18 USPQ2d 1885, 1888 (Fed Cir. 1991); *In re Oetiker*, 24 USPQ2d 1443, 1446 (Fed. Cir. 1992); and *In re Fritch*, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992). The Office Action does not comply with these requirements.

The Office Action states:

> Regarding Claim 20, Nelson et at, hereafter "Nelson," show that it is known to carry out a method of forming a polymeric part for a medical device comprising passing a mass of molten polymer material composition to form an emitted mass (Column 18, lines 12-13), subsequently cooling the emitted mass, without substantially mixing the emitted mass material, whereby the cooled emitted mass comprises at least two regions of material located within the cooled mass in a fixed relationship to each other, said fixed relationship corresponding substantially to the sequence of emission of the polymer material forming each said region (Column 3, lines 51-65; Column 18, lines 36-40; Column 19, lines 52-60), wherein the method further comprises varying an amount of polymer modifier in the polymer composition passing through said opening between the emission of the material forming the first region and the emission of the material forming the second region, whereby at least one of the two regions is provided with a positive amount of the polymer modifier and [at least one of] the two regions are provided with differing amounts of the polymer modifier (Column 2, lines 45-48; Column 3, lines 5 1-65; Column 19, lines 48-55). Nelson does not show using a crystallization modifier as the polymer modifier.

This description of the Nelson reference is not correct. The document does not pertain to a method of forming a polymeric part from molten polymer. Instead it describes methods for forming fiber by *coagulation* of an extruded polymer *emulsion* or *solution*. Further it says nothing about using a "polymer modifier." A specific polymer composition component is taught

to be varied, and that component is a *therapeutic agent*. These misdescriptions clearly evidence an improper hindsight reconstruction of the reference.

The Office further contends

> Katayama et al , hereafter "Katayama," show that it is known to carry out a method wherein a crystallization modifier is used during a polymeric extrusion operation (Column 10, lines 9-16). Katayama and Nelson are combinable because they are concerned with a similar technical field, namely, methods of extruding polymeric articles. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Katayama's crystallization modifier as the polymeric modifier in Nelson's molding process in order to avoid premature crystallization of the polymer, and thus, cause problems in the molding or post-forming steps.

This contention is also untenable as a matter of law. Nelson's invention is specifically directed to a drug releasing biodegradable fiber implant, (see, e.g. Nelson's title). As asserted in the Office Action, the "polymer modifier" is Nelson's therapeutic agent. Consequently, to "use Katayama's crystallization modifier as the polymeric modifier in Nelson's molding process" involves replacing Nelson's therapeutic agents with Katayama's crystallization modifier. The Office Action makes no showing that Katayama's crystallization retarders have any known therapeutic benefit. Such a substitution would result in the loss of the therapeutic effect which is a specific objective of the Nelson disclosure. If Nelson's drug were replaced the implants wouldn't be "drug releasing." Therefore substitution of Katayama's crystallization retarder for Nelson's "polymer modifier" is clearly <u>not</u> motivated.

Furthermore, Katayama describes use of crystallization retarders in polymer compositions used to melt-spin polymer fibers. It says nothing about use of crystallization retarders in the formation of fibers by coagulation of a polymer emulsion or polymer solution. Neither document provides any teaching that provides a reasonable basis for contending that, *with respect to polymer crystallization*, coagulation processes as described by Nelson and melt processes as

described by Katayama have a known equivalence. Consequently Katayama's teachings regarding crystallization retarders are clearly not properly combined with Nelson. The skilled person is provided with no reason to employ a crystallization retarder in Nelson's coagulation system and there is no reason to expect that compounds which retard crystallization from a melt will likely have the same effect in a coagulation system.

At least for the reasons given above the grounds for rejection of claim 20 fail as a matter of law and should be withdrawn.

The arguments asserted against claims 21 and 22, which depend from claim 29 are considered moot in view of the deficiencies in the rejection of claim 20.

The Office Action has not made out a prima facie case of obviousness of claims 20-22. Withdrawal of the obviousness rejection of claims 20-22 is therefore respectfully requested. .

Claim 23 has been rejected under 35 USC §103(a) for obviousness from Nelson and Katayama, further in view of Gahara et al (US 4,950,239). The Office Action relies on Nelson and Katayama in the same way as applied to claim 20. Gahara is only relied upon for the additional feature of claim 23. Gahara does not mention crystallization modifier. In any case it does not cure the deficiencies of the Nelson and Katayama combination which have been articulated in connection with the rejection of claims 20-22. Accordingly withdrawal of the obviousness rejection of claim 23 is also respectfully requested.

Withdrawn Claims

Withdrawn claims 6-7, 9-11, 13-14, 24-26 and 29-30, as currently amended, depend from claim 20 and so should now be examined with the elected method claims 20-23. Claims 6-7, 9-

11, 13-14, 24-26 and 29-30 are non-obvious over the cited documents for at least the reasons given above to overcome the rejections of claims 20-23.

Conclusion

The claims have been confined to the restricted subject matter. The outstanding objections and rejections have been overcome. Accordingly the application is believed to be in condition for allowance. Early and favorable action thereon is respectfully requested.

Respectfully submitted,
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